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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,165	01/30/2004	Euljoon Park	A04P1011	7794
36802	7590	08/30/2006	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			MALAMUD, DEBORAH LESLIE	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/769,165	Applicant(s) PARK ET AL.	
	Examiner Deborah Malamud	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The examiner acknowledges the amendments received 22 June 2006. Claims 1-21 are pending.

Claim Objections

2. Claim 9 is objected to because of the following informalities: it recites the limitation "the rest-indicating sensor" in lines 1-2. This statement lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Applicant's arguments, see "Remarks," filed 22 June 2006, with respect to the rejection of claims 1-21 under Park (U.S. 6,881,192) in view of Katz et al (U.S. 6,580,944), in regards to the common ownership of the Park reference, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Yamanishi et al (U.S. 5,385,144) and Bourgeois et al (U.S. 6,126,611).
5. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanishi et al (U.S. 5,385,144) in view of Bourgeois et al (U.S. 6,126,611). Regarding claims 1, 8 and 13-14, Yamanishi discloses (col. 1, lines 48-65) "a respiration diagnosis apparatus which can, by means of an extremely simple device, either extract

information to distinguish between obstructive apnea and central apnea or automatically perform such differentiation." The respiration diagnosis apparatus employs the information that "the nature of this change in the base line during obstructive apnea is different from that during normal respiration, either automatically differentiates between obstructive apnea and central apnea or extracts information (the amount of change in the base line) to allow performance of such differentiation. In addition, based on this pulse wave signal, the apparatus measures the level of arterial blood oxygen saturation, and based on this measurement differentiates between normal respiration and apnea." The examiner considers this to be a sleep apnea detector to detect when a patient is experiencing an episode of sleep apnea and to differentiate between central sleep apnea and obstructive sleep apnea based on a measured signal. Yamanishi fails to disclose sensing circuitry to sense whether a patient is at rest, further being operative to sense cardiac electrical activity. Bourgeois et al however discloses (col. 3, lines 7-8) a device that "detects low cardiac rates as an indication of resting." The device utilizes an input/output circuit (col. 4, lines 1-6) that "contains the operating input and output analog circuits for digital controlling and timing circuits necessary for the detection of electrical signals derived from the heart, such as the cardiac electrogram." Yamanishi and Bourgeois both disclose systems for diagnosing sleep apnea based on recorded physiological signals. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Yamanishi's central versus obstructive apnea diagnosis system with Bourgeois' cardiac electrogram in order to provide a further physiological parameter for diagnosis confirmation.

6. Regarding claims 2, 4-5, 9-10 and 15, Bourgeois discloses (col. 5, lines 65-67) "if the pulse generator has an activity sensor, switching can automatically occur if body activity less than a pre-determined threshold or minute ventilation indicative of sleep is detected for a predetermined time, e.g. 10 seconds." The examiner considers this to be a device including an activity sensor and a minute ventilation sensor.

7. Regarding claim 3, Yamanishi in view of Bourgeois discloses the claimed invention but does not disclose expressly the accelerometer. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the activity sensor as taught by Bourgeois, with the accelerometer, because the applicant has not disclosed the accelerometer provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the heart activity sensor as taught by Bourgeois, because this sensor is capable of determining whether the patient is at rest. Therefore, it would have been an obvious matter of design choice to modify Yamanishi in view of Bourgeois to obtain the invention as specified in the claim.

8. Regarding claims 6, 11 and 20, Yamanishi discloses (col. 1, lines 66-68; col. 2, lines 1-7) "when obstructive apnea is present, due to the movement of the thorax, internal thoracic pressure changes considerably during attempted respiration, which appears as a sharp change in the base line of the pulse wave signal. In other words, since the waveform of the changed pulse wave signal base line differs from that present normal respiration, obstructive apnea may be distinguished from central apnea by

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detecting the change in the amplitude and/or waveform of the base line of the pulse wave signal." The examiner considers this to be a sleep apnea detector uses amplitude modulation of intracardiac electrogram waveforms to differentiate between the central sleep apnea and the obstructive sleep apnea.

9. Regarding claims 7, 12 and 16, Bourgeois discloses (col. 3, lines 51-56) a pulse generator (Figure 2) for pacing the heart in response to detection of a sleep apnea.

Yamanishi in view of Bourgeois provides a pulse generator that administers different pacing therapies depending on whether central or obstructive apnea is detected.

10. Regarding claims 17-18 and 21, in view of the structure as disclosed by Yamanishi and Bourgeois, the method of operating or using the device would be obvious because it is the normal and logical means by which the device can be used.

11. Regarding claim 19, Bourgeois discloses (col. 6, lines 5-9) "in an alternative arrangement, the mode switch is triggered when arterial or venous oxygen saturation drops below a predetermined level in the absence of any minute ventilation. This predetermined level could be a fixed level or a combination of oxygen saturation decay and a set level." The examiner considers this to be monitoring an oxygen-related parameter.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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